

LEE - Appln. No. 08/966,233

Claim 31 has been rejected as containing new matter. It is the Examiner's position that the hybridization conditions presently recited in claim 31 are not disclosed with respect to the subject matter recited in that claim. This rejection is respectfully traversed.

Applicants note that page 10, lines 3-9, sets forth a definition of a "substantially identical sequence" to Figure 2. From this, it can be inferred that a "substantially identical sequence" to Figure 11A and 11B will have a similar relationship to those Figures. Withdrawal of the rejection is respectfully requested.

Claim 3 was rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to a person of skill in the art that applicant had possession of the claimed invention. It was the Examiner's position that claim 3 was not enabled for hamster GDF-1. The claim has been amended to remove this recitation, thereby rendering this rejection moot.

Claims 3, 11-15, and 24-30 were rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. This rejection is traversed for the following reasons.

It is the Examiner's position that the specification fails to enable how to use the GDF-1 sequences, vectors, host cells and methods of producing protein without undue experimentation. It is respectfully pointed out that Example 5 details how to prepare antisera against GDF-1. Such antisera can be used to characterize GDF-1 at the protein level, to screen for the presence of GDP, and for many other purposes, as will be appreciated by persons of skill in the art. Accordingly, the GDF-1 sequences, vectors, host cells and methods of producing protein will clearly be seen as useful to persons of skill in the art.

Furthermore, Applicant has submitted the Declaration of Ted Ebendal, demonstrating that GDF-1 has biological activity on neurons similar to members of the TGF-beta superfamily of proteins. The Examiner has indicated that this Declaration is insufficient because information presented in the Declaration was not known at the time the application was filed. It is submitted that Applicant stated in the originally filed Declaration that GDF-1 was a new member of the TGF-beta superfamily, and should have similar activities to other members of that family. The evidence presented in the Declaration is in support of that statement, and should thus be accepted for what it demonstrates. Reconsideration is requested.

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Applicant does not agree with the Examiner that uses of the claimed invention disclosed in the application and pointed out in Applicant's previous responses are not enabled. Applicant is not arguing that a person skilled in the art would have to "dream up" potential uses of the present invention. Instead, applicant submits that the Examiner has not explained in previous Office Actions why the objective truth contained in the disclosure is doubted by "evidence or reasoning which is inconsistent with the contested statement". M.P.E.P. 2164.01 and *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971). No such evidence or reasoning was given in the previous Office Actions. Thus, the Examiner's objection appears to be based on the lack of working examples in the specification. However, applicant submits that working examples are not required in order to comply with Section 112, first paragraph, (M.P.E.P. 2164.02) especially in view of the other examples provided in the specification.

For all of the above reasons, withdrawal of the rejection under 35 USC § 112 is respectfully requested.

Claims 3 and 26 were rejected under 35 USC § 112, second paragraph, as being indefinite. Claim 3 was considered to be indefinite in the recitation of "hamster". The claim has been amended to remove this term. Claim 26 was considered unacceptable because it did not refer to an operable linkage

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between the DNA and the vector. The claim has been amended and is believed to be free of the rejection.

All rejections having been addressed, it is respectfully submitted that the application is in condition for allowance, and Notice to that effect is respectfully requested.

Respectfully submitted,

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